pivot MEDICAL

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Section 5. 510(k) Summary

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Date Summary Prepared: November 21, 2012

Device Name

Trade Name:	Knotless Suture Anchor
Common Name:	Bone Anchor
Classification Name:	Smooth or threaded metallic bone fixation fastener
Regulation number:	21 CFR888.3040
Product Code:	MBI

Predicate Devices

Pivot Medical NanoTack Suture Anchor – K110473
Smith & Nephew Knotless Instability Suture Anchor – K093428

Device Description
The Pivot Knotless Suture Anchor is a non-degradable suture anchor manufactured from PEEK-OPTIMA® LT1 polymer attached to / pre-assembled to a stainless steel Inserter. Non-degradable ultra-high molecular weight polyethylene (UHMWPE) blue co-braid #1 suture is provided in the sterile package with the Knotless Suture Anchor and Inserter. The Knotless Suture Anchor with Inserter and Suture is provided as a single use sterile device.

Intended Use
The Knotless Suture Anchor is intended for the fixation of soft tissue to bone in the hip, and is indicated for the reattachment of hip labrum to the acetabulum.

Summary of Technological Characteristics

Pivot Knotless Suture Anchor is an implantable soft tissue fixation device (suture anchor) that allows the physician to secure soft tissue to bone. The Knotless Suture Anchor is made of poly-etheretherketone (PEEK) with an accompanying UHMWPE #1 suture. The Knotless Suture Anchor system includes the Suture Anchor, mounted onto a stainless steel Inserter. The Knotless Suture Anchor is equivalent in materials and design to the Pivot NanoTack Suture Anchor device (K110473) and the Smith & Nephew (S&N) Knotless Instability Suture Anchor (K093428). The only difference between the Knotless Suture Anchor and the Pivot NanoTack Suture Anchor is that the Knotless Suture Anchor has a separate UHMWPE #1 suture while the NanoTack Suture Anchor has a pre-loaded UHMWPE #1 suture. The only difference between the Pivot Knotless Suture Anchor and the S&N Knotless Anchor is that the Pivot Anchor includes the UHMWPE #1 suture within the same package and the S&N does not (provided separately). All components of the Knotless Suture Anchor system are made from biocompatible materials, as is the case for the predicate devices cited.

Summary of Performance Testing

The performance testing conducted demonstrates that the insertion and fixation properties of the Knotless Suture Anchor are substantially equivalent to the NanoTack Suture Anchor.

Pre-clinical testing includes insertion strength, anchor strength, suture strength, and biocompatibility testing.

Summary of Substantial Equivalence

Based upon the indications for use, technological characteristics, and comparison to the predicate devices, the Pivot Knotless Suture Anchor is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 21, 2013

Pivot Medical
% Mr. Jon Cook
Director – Quality Assurance and Regulatory Affairs
247 Humboldt Court
Sunnyvale, California 94089

Re: K123651
Trade/Device Name: Knotless Suture Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: November 21, 2012
Received: November 27, 2012

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K123651

Indications for Use

510(k) Number (if known):

Device Name: Knotless Suture Anchor

Indications for Use:

The Pivot Knotless Suture Anchor is indicated for the reattachment of hip labrum to the acetabulum.

Prescription Use ___X___ AND / OR Over-The-Counter-Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices

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